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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/506,475 | 08/19/2005 | Fredrik Gellerstedt | 1501-1269 | 8910 |
| 465 7590 06/25/2008 YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314 | | | EXAMINER LEWIS, KIM M | |
| | | | ART UNIT 3772 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/506,475

Applicant(s)

GELLERSTEDT ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Detailed Action

DETAILED ACTION

Response to Amendment

1. The amendment filed on 2/15/08 has been received and made of record. As requested, claim 9 has been amended.
2. Claims 1-11 are pending in the instant application.

Allowable Subject Matter

3. The indicated allowability of claims 1-8 and 10-11 is withdrawn in view of the newly discovered reference(s) to WO99/61077. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4, 6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO99/61077 ("Areskoug").

As regards claims 1, 3, 4, 6, 9 and 10, Areskoug discloses a wound dressing that anticipates applicants' presently claimed invention. More specifically, Areskoug discloses a drape/strip in the form of a medical dressing, comprising (1, 2), which on its

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underside is coated with an adhesive partially or fully along at least one edge thereof.

Areskoug discloses the use of Silgel 612, applicants' disclosed adhesive. Thus, the device of Areskoug inherently has all of the claimed adhesive properties as applicants' invention.

Applicant should note that a wound dressing when interpreted broadly is a drape.

As to adhesive reduction note col. 4, lines 15-40.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,310,082 ("Holbrooke") in view of Areskoug.

As regards claim 1, Holbrooke discloses a draping product in the form of a bandage capable of surgical interventions, which on its underside is coated with adhesive along at least one edge thereof (see Figs. 1-4), said coating extending fully or partly along the edge. Holbrooke fails to teach that the adherence force against skin of the adhesive is greater than 0.5 N/25mm, and that the damage to Stratum Corneum of the part of the skin covered by the adhesive is, after removal of the draping product attached to the skin, less than 30%, measured with SCT (Spectroscopic Colour Test).

Areskoug, however, discloses an adhesive medical device comprising the adhesive Silgel 612, which as admitted by applicant, has an adherence force against skin greater than 0.5 N/25mm, and that the damage to Stratum Corneum of the part of the skin covered by the adhesive is, after removal of a draping product attached to the skin, less than 30%, measured with SCT (Spectroscopic Colour Test).

Areskoug teaches that the elastomeric silicone adhesive is skin-friendly will only carry with it a very limited number of stratum corneum cells when removed from the skin. Thus, it would have been obvious to one having ordinary skill in the art to

substitute the adhesive of Steer for the known adhesive taught by Areskoug because of its skin-friendly adhesive properties.

Re. claim 2, Holbrooke discloses the width of the bandage is 25 mm. Thus, the width of the adhesive is 25 mm, thereby being less than 150 mm.

Re. claim 5, as can be seen from Fig. 6, the adhesive is on the to

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Areskoug.

As to claim 8, Areskoug fails to teach that the strip has a width of 25-20 mm. However, it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Thus, it would have been obvious to one having ordinary skill in the art to modify the size of the device of Areskoug in order to fit the area of skin on which it is applied.

11. Claims 1, 5-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,890,608 ("Steer") in view of Areskoug.

As regards claims 1 and 6, Steer discloses an attachment assembly that substantially discloses applicants' presently claimed invention. More specifically, Steer discloses a strip/carrier (constituted by adhesive pad 10 and flange 20), characterized in that the strip/carrier is coated with an adhesive on its underside. Steer fails to teach the adhesive has an adherence force against skin greater than 0.5 N/25mm, and that the damage to Stratum Corneum of the part of the skin covered by the adhesive is, after

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removal of a draping product attached to the skin, less than 30%, measured with SCT (Spectroscopic Colour Test).

Areskoug, however, discloses an adhesive medical device comprising the adhesive Silgel 612, which as admitted by applicant, has an adherence force against skin greater than 0.5 N/25mm, and that the damage to Stratum Comeum of the part of the skin covered by the adhesive is, after removal of a draping product attached to the skin, less than 30%, measured with SCT (Spectroscopic Colour Test).

Areskoug teaches that the elastomeric silicone adhesive is skin-friendly will only carry with it a very limited number of stratum comeum cells when removed from the skin. It would have been obvious to one having ordinary skill in the art to substitute the adhesive of Steer for the known adhesive taught by Areskoug because of its skin-friendly adhesive properties.

With respect to claims 5 and 7, note fastening means (34) of Steer capable of attaching the strip/carrier to the under side of a draping product.

With respect to claim 1, Steer fails to teach the attachment assembly (10, 20) has a width of 25 mm to 200 mm. However, it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Thus, it would have been obvious to one having ordinary skill in the art to modify the size of the device of Steer in order to fit the area of skin on which it is applied.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 2-4, 6 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-5 of copending Application No. 10/508,553 (the '553 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '533 patent recite additional features not present in the claims of the instant invention.

With respect to claim 4, it is inherent that silicone elastomer is hydrophobic.

With respect to claim 6, claim 1 of the '553 application does not recite a strip in the preamble, but recites a draping product. However, in the instant case, the preamble is not limiting, and it would have been obvious to one having ordinary to form the

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draping product into strips, rectangles or squares depending upon the portion of the on which it is applied.

As to the width of the product, the claims of the '553 application fails to recite a width of 25-20 mm. However, it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Thus, it would have been obvious to one having ordinary skill in the art to modify the size of the device of 'the 553 application in order to fit the area of skin on which it is applied.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

kml
June 17, 2008